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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

Stephen Wendell, and Lisa Wendell, for themselves and as successors in interest to Maxx Wendell, deceased

Plaintiff(s),

v.

Johnson & Johnson, et al.

Defendant(s).

CASE NO. C 09-04124 CW

Hearing Date: Thursday, March 13, 2014
Hearing Time: 2:00 p.m.
Hearing Location: Courtroom 2, 4th Floor, 1301 Clay Street Oakland, CA 94612

PLAINTIFFS' REQUEST FOR PERMISSION TO FILE NOTICE OF RECENT DECISION GERMANE TO THE PENDING DEFENDANTS' OMNIBUS MOTION TO EXCLUDE TESTIMONY AND FOR SUMMARY JUDGMENT

TO THE HONORABLE COURT, ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

Pursuant to Civil L.R.7-3(d), Plaintiffs hereby request permission to file a Notice of Recent Decision of the United States District Court for the Northern District of Illinois in the case of *Dolin v. SmithKline Beecham Corp*, No. 12 C 6403 (Zagel, J. Feb. 28, 2014) that is particularly relevant to Defendants' Omnibus Motion to Exclude Testimony and for Summary Judgment that are now pending decision by this Court.

A copy of Plaintiffs' Notice of Recent Decision is attached hereto as Exhibit A.

A proposed form of Order is attached.

Dated: March 5, 2014

Respectfully submitted,
WILLIAMS CUKER BEREZOFSKY, LLC

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EXHIBIT A

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NOTICE OF RECENT DECISION GERMANE TO THE PENDING DEFENDANTS' OMNIBUS MOTION TO EXCLUDE TESTIMONY AND FOR SUMMARY JUDGMENT

TO THE HONORABLE COURT, ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

Plaintiffs hereby respectfully notify the Court of the recent decision of the United States District Court for the Northern District of Illinois in the case of *Dolin v. SmithKline Beecham Corp*, No. 12 C 6403 (Zagel, J. Feb. 28, 2014).

On February 28, 2014, a federal district court judge in Illinois denied a motion for summary judgment brought by defendant GlaxoSmithKline on the identical grounds asserted by defendant Teva in this case, *viz.* that because the plaintiff in that case was taking the generic form of Paxil at the time of his injury, it could not be liable as the brand manufacturer for those injuries. *See Dolin v. SmithKline Beecham*, No. 12 C 6403 (Zagel, J., N.D. Ill. Feb. 28, 2014).1 In a 25 page Memorandum Decision, the court held that GSK could be liable in negligence (but not strict liability) for an inadequate warning as "it was entirely foreseeable that negligence on the part of GSK with respect to paroxetine's design and warning label could result

1 A true and correct copy of that Memorandum Decision is attached hereto as Exhibit 1.

in injury to a consumer ingesting a subsequent generic version of the drug." *Id.* at 10. The court noted that "[u]nder the regulatory scheme created by the Hatch-Waxman Act, whether a consumer ingests the name-brand or generic version of a given drug is immaterial as to the likelihood that negligence in the design or warning label of that drug will cause injury." *Id.*

Respectfully submitted,

WILLIAMS CUKER BEREZOFSKY, LLC

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DATED: March 5, 2014

EXHIBIT 1

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

WENDY DOLIN, Individually and as Independent Executor of the ESTATE OF STEWART DOLIN, deceased,

Plaintiff,

v.

SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, a Pennsylvania Corporation; and MYLAN INC., a Pennsylvania Corporation,

Defendants.

No. 12 C 6403
Judge James B. Zagel

MEMORANDUM OPINION AND ORDER

Plaintiff Wendy B. Dolin has brought this wrongful death action for damages and injunctive relief against defendants SmithKline Beecham Corporation, d/b/a GlaxoSmithKline ("GSK") and Mylan, Inc. GSK now moves for summary judgment pursuant to Fed.R.Civ.P. 56(c), and Mylan moves to dismiss pursuant to Fed.R.Civ.P. 12(b)(6). For the following reasons, GSK's motion for summary judgment is granted in part and denied in part. Mylan's motion to dismiss is granted.

BACKGROUND

Plaintiff Wendy Dolin was married to Stewart Dolin for 35 years. According to the complaint, the Dolins were financially secure, owned their home outright, and had no pressing debts.

In June 2010, Mr. Dolin's family doctor wrote him a prescription for Paxil to treat work-

related anxiety and depression. Paxil is the name-brand version of the drug paroxetine hydrochloride ("paroxetine") and is owned and manufactured by GSK. The drug was first approved for use in the United States in 1992 for treatment of depression in adults.

Mr. Dolin's prescription, however, was ultimately filled with a generic version of paroxetine. Mylan obtained approval to market generic paroxetine in 2007. It is undisputed that the paroxetine Mr. Dolin ultimately ingested was manufactured by Mylan.

On July 15, 2010, six days after beginning to take paroxetine, Mr. Dolin left his office shortly after having returned from lunch with a business associate. He walked to a nearby Chicago Transit Authority Blue Line station at Washington and Dearborn in downtown Chicago. As a northbound train approached the station, Mr. Dolin leaped in front of it to his death. Blood tests taken with Mr. Dolin's autopsy were positive for paroxetine.

The complaint asserts that paroxetine and other similar serotonergic antidepressants called selective serotonin reuptake inhibitors ("SSRIs") can cause an adverse reaction called akathisia, a neurobiological phenomenon marked by profound inner restlessness and agitation. Patients experiencing such a reaction will often exhibit an inability to sit still, pacing and hand-wringing. The complaint asserts that akathisia has long been associated with suicidal behavior.

According to the complaint, Mr. Dolin exhibited classic symptoms of akathisia immediately before his death. A nurse alleged to have been on the platform at the same time as Mr. Dolin noticed that Mr. Dolin was "very agitated, pacing back and forth and looking down the tracks."

The paroxetine label in existence at the time of Mr. Dolin's death, however, did not warn of the drug's association with increased risk of suicidal behavior in adults. Indeed, the label stated that the suicidality risk did not extend beyond the age of 24. Plaintiff asserts that GSK

nevertheless had knowledge that paroxetine use carried a 6.7 times greater risk of suicidal behavior in adults compared to a placebo. Plaintiff asserts that GSK has been aware of paroxetine's association with this increased risk for over 20 years. Plaintiff asserts that GSK concealed the risk, however, and promoted its version of paroxetine, Paxil, as safe and effective.

Plaintiff also alleges that GSK was at least negligent in its manipulation of adverse event data such that the true risk associated with taking paroxetine was obscured. According to the complaint, in GSK's presentation of data on suicidal behavior in patients taking either paroxetine, a placebo, or a comparator drug, GSK included suicide attempts by placebo patients that had taken place before the clinical trial had actually begun. Including these attempts, Plaintiff asserts, yielded a misleading ratio of suicide attempts by paroxetine patients to suicide attempts by placebo patients. The implication is that the connection between paroxetine and suicide attempts was stronger than GSK made it appear.

As to Mylan, Plaintiff asserts that it was aware, or should have been aware, of this undisclosed connection between paroxetine and suicidal behavior, and the misrepresentation of the data supporting it. Nonetheless, Mylan continued manufacturing and selling generic paroxetine without notifying the medical community of the risk associated with its product.

Plaintiff has brought common law negligence and negligent misrepresentation claims as well as product liability claims under theories of both negligence and strict liability against both defendants. In its motion for summary judgment, GSK relies primarily on the argument that, because GSK did not manufacture the pill that Mr. Dolin actually ingested, it is entitled to judgment as a matter of law. Mylan, for its part, argues that Plaintiff's claims as to Mylan are preempted by federal law and must be dismissed.

DISCUSSION

I. GSK's MOTION FOR SUMMARY JUDGMENT

A. Summary Judgment Standard

Summary judgment should be granted when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c). A genuine issue of triable fact exists only if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Pugh v. City of Attica, Ind., 259 F.3d 619, 625 (7th Cir.2001) (citing Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986)).

B. The Hatch-Waxman Act

The tension between the unique federal regulatory scheme governing prescription drugs on the one hand, and Illinois state tort law on the other, is at the heart of the matter currently before the Court. Federal law requires approval from the U.S. Food and Drug Administration ("FDA") before bringing any new drug to market. Approval may be obtained only by filing a New-Drug Application ("NDA") with the FDA. The NDA process is both lengthy and expensive.

In 1984, in an effort to make generic versions of name-brand drugs more widely, safely, and inexpensively available, Congress passed the Drug Price Competition and Patent Term Restoration Act, also commonly known as the Hatch-Waxman Act ("the Act"). The Act provides for an expedited, less costly approval process for generic versions of drugs whose name-brand predecessors have already obtained FDA approval. Once the name-brand manufacturer's patent expires, generic manufacturers are able to enter the market with the benefit

of a far more streamlined approval process. This generic drug application process is referred to as the Abbreviated New Drug Application ("ANDA").

One caveat of this approach, however, is that the generic drug's design and warning label must identically match that of the name-brand version of the drug in all material respects. As the Supreme Court recently summarized:

> First, the proposed generic drug must be chemically equivalent to the approved brand-name drug: it must have the same "active ingredient" or "active ingredients," "route of administration," "dosage form," and "strength" as its brand-name counterpart. 21 U.S.C. §§ 355(j)(2)(A)(ii) and (iii). Second, a proposed generic must be "bioequivalent" to an approved brand-name drug. § 355(j)(2)(A)(iv). That is, it must have the same "rate and extent of absorption" as the brand-name drug. § 355(j)(8)(B). Third, the generic drug manufacturer must show that "the labeling proposed for the new drug is the same as the labeling approved for the [approved brand-name] drug." § 355(j)(2)(A)(v).

Mutual Pharmaceutical Co., Inc. v. Bartlett, 133 S.Ct. 2466, 2471 (2013).

Once an NDA or ANDA has been approved, the manufacturer is prohibited from making any material changes to the drug's design. 21 C.F.R. § 314.70(b). Further, generic manufacturers (though, significantly, not name-brand manufacturers) are also prohibited from making unilateral changes to the drug's warning label. *See* § 314.150(b)(10).

Notably, in an effort to ensure that these reduced barriers to competitors' entry into the marketplace did not stymie innovation, the Act also allows for the extension of the patent protection period to afford name-brand manufacturers a longer period of time to recoup their investment in successful drugs.

The tension between this regulatory scheme and state tort law came to a head in *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567 (2011). The plaintiffs in *Mensing* were prescribed Reglan, the name-brand iteration of metoclopramide, a drug commonly used to treat digestive tract problems. *Id*. at 2572-73. The plaintiffs asserted that their long-term use of the drug caused them to

develop tardive dyskinesia, a severe neurological disorder, and they alleged that the warning labels in connection with the drug inadequate. *Id*. at 2573.

Although the plaintiffs were prescribed Reglan, their respective pharmacists filled the prescriptions with the generic equivalent, consistent with their respective states' drug-substitution laws.[1] This would prove disastrous to their claim. The plaintiffs duly filed suit against the manufacturer of the pills they ingested, generic metoclopramide, claiming an inadequate warning label. The Supreme Court, however, found that the claim was preempted by federal law, specifically, the Hatch-Waxman Act. *Id*. at 2577-78.

Hatch-Waxman prohibits a generic manufacturer from unilaterally making changes to its drug's warning label. The Court concluded that, with respect to any alleged defects in connection with a generic drug's warning label, a generic manufacturer's hands are simply tied. "If the Manufacturers had independently changed their labels to satisfy their state-law duty, they would have violated federal law." *Id*. at 2578. Federal law preempted the plaintiffs' claim.

Two years earlier, the Court had found the same did not hold true for name-brand manufacturers. In *Wyeth, Inc. v. Levine*, 555 U.S. 555 (2009), the plaintiff claimed that a name-brand manufacturer was negligent in connection with a warning label, and the Court found that the discretion afforded name-brand manufacturers under the Act avoided any preemption problem. *See id*. at 581. Hatch-Waxman allowed name-brand manufacturers the latitude necessary to make changes to the label and satisfy their state tort law duties.

Crucial to *Levine* is the fact that the plaintiff ingested the name-brand version of the drug. The name-brand manufacturer sued by the plaintiff actually manufactured the pill ingested by the plaintiff. As in *Levine*, the name-brand manufacturer of the drug is sued here, but Mr. Dolin indisputably ingested a generic version of the drug. What legal recourse a plaintiff has under

[1] *See* 225 ILCS 85/25 for the analog in Illinois.

such circumstances appears to be a question of first impression in Illinois and in the Seventh Circuit.[2]

C. Plaintiff's Common Law Negligence Claims

1. *Common Law Negligence or Products Liability?*

At the threshold, GSK argues that Plaintiff's common law negligence claims are de facto products liability claims, merely "disguised" as claims sounding in common law negligence. In GSK's view, bringing a products liability claim against GSK on these facts is a non-starter, because the "product" alleged to have caused the injury at issue was not manufactured by GSK. At least on the face of it, construing Plaintiff's common law negligence claims as product liability claims certainly would serve GSK's ends.

Is the Court compelled to accept GSK's construction of this plaintiff's claims? Some states statutorily define what constitutes a products liability claim. For example, Arkansas state law defines a products liability action as "*all actions* brought for or on account of personal injury, death, or property damage caused by or resulting from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning, instruction, marketing packaging, or labeling of any product." A.C.A. § 16-116-102 (emphasis added); *see also, e.g.*, O.R.S. § 30.900. Were actions brought by Illinois plaintiffs similarly constrained, GSK's argument might find more purchase here. *Cf. Phelps v. Wyeth, Inc.*, 857 F.Supp.2d 1114, 1121 (D.Or. 2012). Yet while states like Arkansas have decreed by statute that an action brought for injury caused by the design or warning of a product is necessarily a "product liability action,"

[2] Background reading for those unfamiliar with this legal problem includes: *Foster v. American Home Products Corp.*, 29 F.3d 165 (4th Cir. 1994); *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89 (1st Dist. 2008); Victor E. Schwartz, Phil Goldberg, Cary Silverman, *Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm was Allegedly Caused by Generic Drugs has Severe Side Effects*, 81 Fordham L. Rev. 1835 (2013); Allen Rostron, *Prescription for Fairness: A New Approach to Tort Liability of Brand-Name and Generic Drug Manufacturers*, 60 Duke L.J. 1123 (2011).

Illinois has not.[3]

Nothing in Illinois common law compels a court to construe Plaintiff's common law negligence claims as product liability claims either. The injury here did indeed occur in connection with a product. And GSK manufactures products. Yet Plaintiff has not brought suit against GSK for tortious conduct committed strictly as a manufacturer of products. And, though GSK implicitly urges to the contrary, I see no reason why all suits brought against GSK must be brought against GSK *qua* manufacturer.

In addition to manufacturing one particular version of paroxetine (Paxil), GSK was responsible for paroxetine's design and warning label. And GSK vigorously contends that the design and warning label are not in themselves "products." GSK has not shown why Plaintiff should be precluded from claiming at common law that GSK, independent of its capacity as a manufacturer of one particular iteration of paroxetine, was negligent in connection with its responsibility for these "non-products," and that this negligence contributed to her injury.[4]

Having concluded that there is nothing fundamentally improper about analyzing Plaintiff's common law negligence claims as such, the inquiry turns to whether Plaintiff's complaint is sufficient to withstand GSK's motion for summary judgment.

2. *Negligence Analysis*

To claim common law negligence, a plaintiff must allege facts establishing a duty of care owed by the defendant to the plaintiff, a breach of that duty, and an injury proximately caused by the breach. *Simpkins v. CSX Transportation, Inc.*, 965 N.E.2d 1092, 1096 (Ill. 2012). Whether a

[3] A 1995 amendment to the Illinois Code of Civil Procedure endeavored to establish a definition of product liability actions similar to that found in Arkansas and other states. The amended statute was subsequently held unconstitutional in its entirety, however, and no revised version has been enacted since. *See* 735 ILCS 5/2-201; *see also Best v. Taylor Machine Works*, 179 Ill.2d 367, 467 (Ill. 1997); *Whelchel v. Briggs & Stratton Corp.*, 850 F.Supp.2d 926, 932, n. 4 (N.D.Ill. 2012) (briefly describing the legislative history and noting that courts must analyze a defendant's argument under the version of the statute that existed prior to the ill-fated 1995 amendments).

[4] *See also* section I.C.3.ii, *infra*.

duty exists is a question of law for the court to decide. *Id*.

In Illinois, "the touchstone of [a] court's duty analysis is to ask whether a plaintiff and a defendant stood in such a relationship to one another that the law imposed upon the defendant an obligation of reasonable conduct for the benefit of the plaintiff." *Id*. at 1097. Significantly, however, whether a duty exists "does not depend upon contract, privity of interest, or the proximity of relationship, but extends to remote and unknown persons." *Id*. There need not be a direct relationship between the parties. *Id*. Rather, "[t]he 'relationship' referred to in this context acts as a shorthand description for the sum of four factors:

> (1) the reasonable foreseeability of the injury;
> (2) the likelihood of the injury;
> (3) the magnitude of the burden of guarding against the injury; and
> (4) the consequences of placing that burden on the defendant."

Id.

So on the one hand, a duty does not depend on the proximity of relationship and extends to remote and unknown persons. On the other hand, the Illinois Supreme Court has also made clear that there is no "duty to the world at large." *Id*. The sum of these four factors, referred to as the "relationship" between the parties, is the limiting principle that allows for the former but stops short of the latter. *See id*.

Numerous courts outside of Illinois and the Seventh Circuit take a dim view of the notion that a name-brand defendant such as GSK might owe a duty of care to a consumer of the generic version of one of its drugs. *See Foster v. American Home Products Corp.*, 29 F.3d 165 (4th Cir. 1994); *see also Smith v. Wyeth, Inc.*, 657 F.3d 420, 424 (6th Cir. 2011); *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 613-14 (8th Cir. 2009); *Strayhorn v. Wyeth Pharmaceuticals, Inc.*, 882 F.Supp.2d 1020, 1029-30 (W.D.Tenn. 2012); *Phelps*, 857 F.Supp.2d at 1121; *Metz v. Wyeth LLC*, 830 F.Supp.2d 1291, 1293 (M.D.Fla. 2011) (collecting cases); *but see Conte v. Wyeth, Inc.*, 168 Cal.

App. 4th 89 (1st Dist. 2008). These judges may well be right, but I am not yet ready to join their opinions.

Plaintiff has alleged that GSK was at least negligent in connection with paroxetine's design and warning label. Construing all facts in Plaintiff's favor for purposes of this motion, *see Srail v. Village of Lisle, Ill.*, 588 F.3d 940, 948 (7th Cir. 2009), the foreseeability of Plaintiff's injury as a result of such negligence should not be controversial. First, once GSK's patent protection for paroxetine expired, it was no surprise that another manufacturer would begin producing a generic version of the drug, and that consumers in the market for Paxil would begin purchasing it.[5] And it was well understood that any generic manufacturer would be required by law to use GSK's design and warning label, and that any defects later discovered could only be cured by GSK. Under such circumstances, it was entirely foreseeable that negligence on the part of GSK with respect to paroxetine's design and warning label could result in injury to a consumer ingesting a subsequent generic version of the drug.

Continuing with the duty inquiry described above, and again construing all facts and drawing all reasonable inferences in Plaintiff's favor, GSK has not shown why the likelihood of injury was so remote as to undo GSK's duty of care. The principal distinction GSK insists upon – that Mr. Dolin did not ingest a product that GSK manufactured – does not lessen the likelihood that GSK's allegedly tortious conduct would lead to Plaintiff's injury. Under the regulatory scheme created by the Hatch-Waxman Act, whether a consumer ingests the name-brand or generic version of a given drug is immaterial as to the likelihood that negligence in the design or warning label of that drug will cause injury.

[5] Every state has now enacted drug substitution laws, requiring pharmacists under most circumstances to substitute available generic drugs for name-brand drugs when filling prescriptions. Schwartz, Goldberg, Silverman, *Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm was Allegedly Caused by Generic Drugs has Severe Side Effects*, 81 Fordham L. Rev. at 1847-48. On average, the generic version of a drug now seizes 80 percent of name-brand sales, up from 79 percent in 2010 and 63 percent in 2006. *Id.*

The third and fourth considerations, the magnitude of the burden of guarding against the injury, and the consequences of placing that burden on the defendant, are closely related. Guarding against the injury alleged here, however, could be as simple as updating the warning label. There may well be something to be said for "over-warning," and the problem of inadvertently deterring consumers from talking medication that would genuinely help them. But there is nothing yet in the record here to suggest that this problem is so grave as to warrant finding that GSK owed no duty of care to Plaintiff. And GSK does not make the argument.

That GSK did not manufacture the pill Mr. Dolin ingested is largely immaterial on this point. A problem with paroxetine's warning label and design will impact the name-brand version of the drug manufactured by GSK and any generic versions of the drug equally. The same "fix" will be required. GSK will not be tasked with the burden of crafting one new warning label for Paxil, and then other discrete warnings for various generic iterations of the drug – that all of the iterations of paroxetine are bio-equivalent and require the same warning is precisely the point. Further, GSK has been compensated for taking responsibility for paroxetine's design and warning label with an extended period of government-protected monopoly privileges in connection with the sale of its particular version of paroxetine, Paxil.

In sum, consideration of these four factors on this record leads to a conclusion that these parties stood in a relationship to one another that, while clearly not "direct," was sufficient for the law to impose a duty of reasonable conduct upon GSK for the benefit of Plaintiff. *See Simpkins*, 965 N.E.2d at 1097. With respect to breach, the complaint contains specific allegations regarding GSK's use of scientifically questionable methods to assess and report the presence of adverse side effects in connection paroxetine. It also sets forth specific allegations regarding GSK's failure to update paroxetine's warning label in 2007, despite having knowledge

of clinical studies apparently indicating that an update was called for. Plaintiff has raised a genuine issue of material fact as to whether GSK, through this and other allegedly negligent conduct, breached its duty, proximately causing Plaintiff's injury. [6]

3. *GSK's Counter-Argument: Mr. Dolin Did Not Ingest GSK's "Product"*

i. Did GSK Contribute to a Risk of Harm?

GSK argues that Plaintiff cannot even satisfy the threshold requirement that GSK must be shown to have created or contributed to a risk of harm to the plaintiff. *See id*. at 1098. "Because Mr. Dolin did not ingest GSK's product Paxil before his death," GSK asserts, "Paxil did not and could not cause his death." Def. Reply at 17. Yet while it is clear that GSK did not manufacture the version of paroxetine that Mr. Dolin ingested, GSK does more than simply manufacture its own version of the drug. And as noted above, GSK has offered no reason why it should be held liable only for those injuries caused by its negligence as a manufacturer.[7]

As the patent holder, GSK was responsible for paroxetine's design and warning label. Under the Hatch-Waxman Act, only GSK was legally permitted to cure any warning label defects. GSK is alleged to have been negligent with respect to paroxetine's design and warning label, and, if true, such negligence would necessarily contribute to a risk of harm to the consumers of any iteration of paroxetine, whether the name-brand version that GSK happens to manufacture, or another's company's generic version of the drug.

ii. Must GSK's "Product" Actually Have Caused the Injury?

GSK argues that, even if GSK did contribute to a risk of harm to the plaintiff, the

[6] GSK does little to refute these assertions or otherwise contest Plaintiff's claim on the merits, electing instead to rest almost entirely on the argument that consumers of generic drugs simply cannot bring claims for injury against the drug's name-brand manufacturer. I anticipate that a second motion for summary judgment, this one actually addressing the merits of the claim, will be forthcoming.

[7] As will be discussed in section I.D.2, *infra*, it is not clear that this reasoning applies with equal force in the strict liability context.

relationship between the parties is nevertheless too remote to impose a duty on GSK. "[I]n order to recover in a products liability action under Illinois law, regardless of the theory alleged, it is axiomatic that a plaintiff must show that the defendant's product *actually caused* the alleged injuries." Def. Brief in Support of MSJ, p. 13 (emphasis in original). "No duty is imposed upon a manufacturer that did not manufacture the product at issue." *Id*. at 18. And, "while a manufacturer owes a duty to plaintiffs who will use its drug…the duty is not so broad as to extend to anyone who uses the type of drug manufactured by a defendant." *Id*. (citing *Smith v. Eli Lilly & Co.*, 137 Ill.2d 222, 265 (Ill. 1990)).

This argument has a certain surface appeal, but on the facts claimed here, it suffers from two flaws.

First, as noted in section I.C.1, *supra*, I see no reason why all of Plaintiff's claims must be viewed and analyzed through the rubric of product liability law. GSK's position on this point is troubling in that it seeks to have things both ways. GSK vigorously contends that paroxetine's warning label and design are not products, and that GSK cannot, therefore, be held liable as their manufacturer. A reasonable argument can be made in support of that position. But it is something of an overreach when GSK *also* contends that alleging negligence on GSK's part in connection with the warning label and design must nevertheless be construed as a *product* liability claim – a product liability claim that Plaintiff cannot win because her husband did not ingest GSK's "product." *Cf. Chatman v. Pfizer, Inc.*, 2013 WL 1305506, *9 (S.D.Miss. March 28, 2013).

Another flaw in this argument is that it conflates two facially similar, but fundamentally distinct, tort liability problems. One is the problem actually at issue here. It arises when an injury occurs in connection with a given product, and a plaintiff asserts that tortious conduct by

someone other than the product's manufacturer caused or contributed to the injury.[8]

The other is the distinct problem of indeterminate tortfeasors. This arises when a plaintiff is injured by a product, but is unsure as to which manufacturer among the numerous manufacturers of similar products was responsible for the particular product with which the plaintiff came into contact.

Illinois Courts have taken a dim view of claims burdened by this latter difficulty. As GSK notes, a manufacturer cannot be held liable "without proof that the particular [manufacturer's] specific product caused the injury for which recovery is sought." *Lewis v. Lead Indus. Ass'n, Inc.*, Ill. App. 3d 95, 102-03 (1st Dist. 2003). And, "[t]he fact that over 300 companies sold a similar product for similar purposes cannot fairly be held to have created a sufficient nexus such that each company can be responsible for the injuries caused by others' products." *Smith*, 137 Ill.2d at 260.

Where a plaintiff is injured by a product, but is unable to identify the manufacturer responsible for the product, Illinois will not permit a claim brought against another manufacturer of a similar product. A manufacturer's duty is not "so broad as to extend to anyone who uses or might be injured by a like-kind product supplied by another." *Lewis*, Ill. App. 3d at 103. This is true, even where it can be shown that all of the manufacturers were similarly negligent. *See*

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[8] *See* Madden & Owen on Products Liability, § 19:4 (collecting cases); Melissa Evans Bush, Products Liability and IP Licensors, 22 Wm Mitchell L Rev. 299, 311-14 (2000) (collecting cases). A review of cases of this type reveals that most involve a non-manufacturing defendant that is hired to perform some service in connection with the product, often developing its design. At least one Illinois Appellate Court has held that such defendants may be found liable for negligence, but that they may not be held strictly liable. *Mechanical Rubber & Supply Co. v. Caterpillar Tracker Co.*, 80 Ill. App.3d 262, 264 (3d. Dist. 1980); *see also* section I.D.2, *infra*.

The prescription drug scenario may be unique in this context, insofar as the name-brand company provides its design and warning label to the generic company, not voluntarily, but at the direction of the Hatch-Waxman Act. On the other hand, the Act does compensate the name-brand company for this "service" in the form of an extended period of government-protected monopoly control over the sale of the product. Further, that the name-brand company will be expected to provide this information is readily foreseeable, and the identity of the particular company that will make use of the information is readily ascertainable. Further still, the name-brand company maintains control over the design and warning label in accordance with the Act.

Smith, 137 Ill.2d at 266. Causation cannot be ignored. Each of the manufacturers may have been similarly negligent, but only one actually caused the plaintiff's injury, and the plaintiff must be able to identify *that* manufacturer in order to proceed with his or her claim. *See id*.

It is unclear, however, what work this line of reasoning does toward resolving the question actually before the Court.

Plaintiff here *can* identify the entity she alleges to have actually caused her injury. If Plaintiff were suing GSK for negligence in manufacturing its version of paroxetine when in fact it was the negligence of some other unknown paroxetine manufacturer that actually caused Plaintiff's injury, much of the product identification case law to which GSK cites may well have been controlling. But that is not the limited claim here. GSK is being sued for its alleged negligence in connection with paroxetine's design and warning label. GSK ultimately employed that design and label in Paxil, the version of paroxetine that GSK manufactures, but GSK has not shown why that is material in this context. The negligence here is extrinsic to the Paxil manufacturing process, and, if true, it could proximately cause injury to consumers of all versions of paroxetine, including the generic version that Mr. Dolin ingested.

Taken out of context, language in product identification cases like *Smith* and *Lewis* may well appear to support GSK's argument. In truth, the principles for which that line of cases stands are inapposite here.

iii. *Foster v. American Home Products Corp.*

It is difficult to criticize GSK for offering the "this was not our product" argument. It was presented stridently by the defendant name-brand manufacturer in the leading case dealing with this question, and, there, the Court accepted it. *See Foster*, 29 F.3d at 168; *Foster*, Brief for Appellee at 9-16. Numerous courts have subsequently cited *Foster* with approval. *See Smith*,

657 F.3d at 424; *Mensing*, 588 F.3d at 613-14; *Strayhorn*, 882 F.Supp.2d at 1029-30; *Phelps*, 857 F.Supp.2d at 1121; *Metz*, 830 F.Supp.2d at 1293 (collecting cases). Yet neither *Foster*, nor any of the courts relying on *Foster*, addressed the issue discussed above – whether a plaintiff injured by a product may assert that tortious conduct on the part of someone other than the product's manufacturer and extrinsic to the manufacturing process contributed to the injury.

As in this case, the *Foster* Court was asked whether a name-brand defendant stood in such a relationship with a consumer of a generic version of one of its products so as to owe that consumer a duty of care. *See Foster*, 29 F.3d at 171. The *Foster* Court held that there was "no such relationship" because the plaintiff was "injured by a product that [the defendant] did not manufacture." *Id*.

The *Foster* Court, as GSK urges here, analyzed the complaint as though it presented an indeterminate tortfeasor problem. *Compare Foster*, 29 F.3d at 168 (and cases cited) *with* GSK Reply, p. 12. Where a plaintiff is unsure as to the identity of the manufacturer that actually produced the injury-causing product, that plaintiff cannot simply bring suit against any manufacturer that produces similar products. *See Foster*, 29 F.3d at 168; *Lewis*, Ill. App. 3d at 102-03. A manufacturer is not liable for injuries caused by the products of other manufacturers. *See Foster*, 29 F.3d at 168; *Foster*, Brief for Appellee at 13.

Yet to suggest that the question actually raised here is simply whether GSK may be held liable for injuries caused by a product that Mylan manufactured is incomplete and misleading. The question is whether GSK, though not the pill's manufacturer, may nevertheless be held liable for tortious conduct that was extrinsic to the manufacturing process and that contributed to Plaintiff's injury. Plaintiff has not failed to identify the "true" manufacturer of the product in question. The claim is not brought against GSK in lieu of the company that actually

manufactured the pill Mr. Dolin ingested. The claim is brought against GSK because GSK – not Mylan – was actually responsible for the pill's design and warning label. *Smith*, *Lewis*, and the other cases relied upon by GSK and *Foster* undermine only the former type of claim. In my view, they are inapposite to the claim before the Court, and *Foster* is not persuasive here.

4. *Negligent Misrepresentation*

The foregoing duty analysis and conclusion apply with equal force to Plaintiff's negligent misrepresentation claim. To state a claim for negligent misrepresentation, a plaintiff must show: (1) a false statement of material fact; (2) negligence on the part of the defendant in ascertaining the truth; (3) intention to induce the other party to act; (4) action by the other party in reliance on the truth of the statements; and (5) damage to the other party resulting from such reliance. *See Board of Educ. of City of Chicago v. A,C and S, Inc.*, 131 Ill.2d 428, 452 (Ill. 1989).

I find that Plaintiff's case with respect to these elements is sufficient to survive GSK's motion for judgment.

GSK asserts that Plaintiff cannot show that GSK intended to induce Mr. Dolin to act. It "belies common sense," GSK contends, to argue that GSK intended to induce Mr. Dolin to purchase one of GSK's competitor's products. This argument simply manipulates what is little more than a level of abstraction problem. Given GSK's version of paroxetine and a competitor's version of paroxetine, there is no doubt that GSK would want consumers to purchase GSK's version, Paxil. And, indeed, Mr. Dolin's physician prescribed Paxil for him.

Taking a slightly broader view, however, it is certain that GSK intended for consumers to trust that paroxetine was a safe and effective drug. For consumers to believe otherwise would be adverse to GSK's interests. Consistent with Illinois generic drug substitution law, Mr. Dolin's prescription was ultimately filled with the generic equivalent to Paxil. But GSK's interests with

respect to general public acceptance of the safety of all paroxetine is, in my view, sufficient to undermine GSK's argument that they did not intend to induce Mr. Dolin to act.

GSK next argues that Plaintiff cannot satisfy the reliance requirement because Plaintiff alleges that misrepresentations were made only to Mr. Dolin's physician and not directly to Mr. Dolin. This turns principles undergirding the learned intermediary doctrine on their head. First, the complaint does allege that GSK's misrepresentations were made to Mr. Dolin. Complaint ¶124. But it is in any event clear that GSK knew the information would be used and relied upon by physicians, and that the expertise of these learned intermediaries would then be relied upon by patients. Unsurprisingly, that is what is alleged to have happened here. *Cf. Quinn v. McGraw-Hill Companies, Inc.*, 168 F.3d 331, 335 (7th Cir. 1999); *Smith v. Boehringer Ingelheim Pharmaceuticals, Inc.*, 886 F.Supp.2d 911, 927-28 (S.D.Ill. 2012).

GSK urges essentially the same arguments in opposition to Plaintiff's fraud-based claims.[9] They are similarly lacking in merit. The complaint demonstrates genuine issues of material fact in connection with these claims as well, and it is sufficient to withstand GSK's summary judgment motion.

D. Plaintiff's Product Liability Claims

A product liability claim may be brought under a theory of negligence, or a theory of strict liability. *Blue v. Environmental Engineering, Inc.*, 215 Ill.2d 78, 89 (Ill. 2005). "Illinois cases considering a cause of action for defective products liability sounding in negligence rather than strict liability are rare, probably because it appears to plaintiffs that it is easier to prove the strict liability count." *Id.* at 95 (noting that this is certainly true when speaking of a manufacturing defect, but that a design defect claim is more akin to a negligence claim).

For a plaintiff to prevail under either theory, the product must be shown to be

[9] *See* note 6 and accompanying text.

unreasonably dangerous. *See Mikolajczyk v. Ford Motor Co.*, 231 Ill.2d 516, 525 (Ill. 2008) (as to strict liability); *Calles v. Scripto-Tokai Corp.*, 224 Ill.2d 247, 270-71 (Ill. 2007) (as to negligence). Generally, there are three ways a product alleged to have caused injury may be found to be defective and thus unreasonably dangerous. The product may contain a manufacturing defect, it may be defective in design, or it may be rendered defective due to inadequate instructions or warnings. *Blue*, 215 Ill.2d at 93.

Whether a product is defective is ordinarily a question of fact for the jury to decide. *Korando v. Uniroyal Goodrich Tire Co.*, 159 Ill.2d 335, 344 (Ill. 1994). Here, Plaintiff asserts that the pill ingested by Mr. Dolin was defective by virtue of its design and by virtue of an inadequate warning label.

1. *Products Liability – Negligence Theory*

In Illinois, a product liability action asserting a claim that is based on negligence falls within the framework of common law negligence. *Calles*, 224 Ill.2d at 270. One might then ask what work is done by distinguishing a given common law negligence claim as a "product liability claim based on negligence." In my view, recognizing the distinction contributes little to the analysis.

The only material difference appears to be that the duty analysis in a "product liability claim based on negligence" is short-circuited with a presumption. That is, it is presumed that a "manufacturer has a non-delegable duty to design reasonably safe products." *Id.*

This "product liability based" understanding of duty presents something of an awkward fit for Plaintiff here. As GSK emphasizes, it is the "manufacturer" that owes a duty to design reasonably safe products. And GSK did not manufacture the pill that Mr. Dolin ingested. This apparent tension could be reconciled by adopting a more expansive understanding of what it is to

be a "manufacturer" for purposes of the duty analysis.[10] In my view, however, the more sensible analysis simply concludes that such claims exist outside of the product liability framework.[11]

In any event, the practical impact of this distinction on the viability of Plaintiff's negligence claim is minimal. Whether it is understood to be inside or outside the rubric of products liability, the claim and analysis still fall within the framework of common law negligence, and the same elements must be pled and proved. *See Calles*, 224 Ill.2d at 270. The only difference is that, understood as a claim outside the rubric of products liability, Plaintiff must actually contend with the duty element, rather than benefit from the presumed duty manufacturers owe to consumers of their products.[12]

As discussed in section I.C.2, *supra*, I find that, under the complaint's allegations, GSK did indeed owe a duty of care to Plaintiff. This conclusion arises from a duty analysis under Illinois common law. With respect to Plaintiff's negligence claims, then, whether GSK is a "manufacturer" in the context of this case and for purposes of the duty owed by manufacturers to design reasonably safe products is immaterial. So too is any effort to distinguish Plaintiff's common law negligence claims as product liability claims, insofar as they are product liability claims brought on a theory of negligence.

2. *Product Liability – Strict Liability Theory*

Plaintiff's product liability claims brought under a theory of strict liability encounter greater obstacles. Under a strict liability theory, a plaintiff may prevail on a product liability claim without showing fault on the part of the defendant. *See Calles*, 224 Ill.2d at 270. In the absence of the burden to show fault however, a strict product liability claim must satisfy other criteria.

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[10] *See* section I.D.2, *infra*.
[11] *See* sections I.C.1, *supra*.
[12] *See* section I.C.2, *supra*.

To recover in a product liability action under strict liability in Illinois, a plaintiff must plead and prove that the injury complained of resulted from a condition of the product, that the condition was unreasonably dangerous, and that it existed at the time the product left the manufacturer's control. *Mikolajczyk v. Ford Motor Co.*, 231 Ill.2d 516, 525 (Ill. 2008). Strict liability for injuries resulting from a defective product may be found against persons in the "distributive chain," including manufacturers, suppliers, distributors, wholesalers and retailers. *See Hammond v. North American Asbestos Corp.*, 97 Ill.2d 195, 206 (Ill. 1983).

Again, a product may be found to be defective and thus unreasonably dangerous by virtue of a manufacturing defect, a design defect, or an inadequate warning. Under the Hatch-Waxman Act, however, the company responsible for a given product's design and warning is not necessarily the manufacturer and does not necessarily fall anywhere within the distributive chain.[13]

And there lies the difficulty for this plaintiff and others similarly situated. A theory of product liability law that holds strictly liable only manufacturers and companies within the product's distributive chain cannot easily accommodate a regulatory scheme that severs the responsibility for manufacturing and distributing the product from the responsibility for its design and attendant warning, assigning the former to one company, and the latter to another.

Under the Act, whether Mr. Dolin ingested a generic version of paroxetine or the name-brand version of paroxetine, GSK had control over its design and warning. And yet GSK only manufactured, and under Illinois product liability law apparently can only be held strictly liable for, the name-brand version.

In an effort to reconcile this inherent tension a court might simply adopt a more expansive view of product liability law. For example, and as Plaintiff urges, one might conceive

[13] *See* section I.B, *supra*.

of the drug's design or its warning label as the "product" that is actually at issue here. Such an understanding would put GSK in the chain of production, regardless of which version of paroxetine Mr. Dolin actually consumed. In my view, however, clear policy concerns undergirding the doctrine of strict product liability counsel against so expansive an understanding of the law.

Strict product liability acknowledges that products will sometimes cause injury, even in the absence of fault. Holding manufacturers and others in the chain of distribution liable for these faultless injuries reflects a policy decision to burden sellers, rather than consumers, with this risk.

> [P]ublic policy demands that the burden of accidental injuries caused by products intended for consumption be placed upon those who market them, and be treated as a cost of production against which liability insurance can be obtained; and that the consumer of such products is entitled to the maximum of protection at the hands of someone, and the proper persons to afford it are those who market the products.

Restatement (Second) of Torts § 402A, Comment *c* (1965).

In the case of prescription drugs, when a brand-name manufacturer's patent expires, and another company begins manufacturing a generic version of the drug, the availability and use of the drug generally will expand dramatically. Indeed, this was one of the Hatch-Waxman Act's principal aims. To the extent use of the drug comes with a risk of injury, however, this increase in use comes with a correlative increase in exposure to that risk.

But to hold a name-brand manufacturer strictly liable for injuries caused by a drug's defective design or warning when a *generic* version of the drug is purchased and ingested is not to treat the injury "as a cost of production," or to allocate the cost to "those who market the products." *See* Restatement (Second) of Torts § 402A, Comment *c* (1965). The name-brand manufacturer is outside the chain of distribution and does not benefit from the sale of the generic

version of the drug. To hold the name-brand manufacturer liable for injuries caused by a defective design or warning when a generic version of the drug was ingested is to treat the injuries as a cost of production of the *name-brand* version of the drug.

To be sure, a name-brand manufacturer could account for this cost by raising the price it charges for the name-brand drug. And it is also reasonable to note, as does Plaintiff, that Hatch-Waxman compensates name-brand manufacturers for the mandated sharing of their designs and warning labels with competitors in the form of a more lengthy period of government-protected monopoly control over their products. But these points do not persuade me that holding a name-brand manufacturer strictly liable for an injury resulting from contact with a generic version of the drug is consistent with the policies underlying strict liability theory.

First, a quite substantial portion of name-brand sales naturally occurs prior to the expiration of the name-brand manufacturer's patent protection – that is, before a generic manufacturer has even entered the market. Raising prices in an effort to account for the total cost of injuries that will result when unknown future generic manufacturers enter the market and bring an unknown and possibly incalculable increase in the drug's availability and use hardly seems plausible.

Second, and in any event, strict product liability theory anticipates that, as increasing sales increase a manufacturer's exposure to the risk that the use of its product will actually lead to injury, there will be a proportionate increase in earnings over which to spread the cost of those injuries. The rationale for holding manufacturers responsible for the cost of accidental injuries caused by their products is that those who market the products are the "proper persons to afford it." Here, the name-brand manufacturer sees no proportionate increase in earnings commensurate with the increased risk exposure. In my view, to hold a name-brand manufacturer

strictly liable under such circumstances is at odds with policy underlying strict liability theory.

This reasoning does not hold where a name-brand manufacturer is found, not strictly liable, but liable for negligence. An injury (or at least liability for an injury) that occurs due to negligence can be avoided simply by satisfying one's duty of care. Significantly, this is so without regard to whether the name-brand or generic version of the drug was consumed. Where a company's negligence in connection with a product causes injury, it may naturally be held liable for having caused that injury. Where there is no fault, however, the public policy rationale that justifies burdening the seller with the cost of injury rather than the consumer does not merit placing liability on an entity whose benefit from the sale is so remote, and whose ability to account for the cost is so limited.

II. MYLAN's MOTION TO DISMISS

On June 24, 2013 the United States Supreme Court issued its decision in *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 133 S.Ct. 2466 (2013), a case which appears to control the claim Plaintiff has brought against Mylan, the company that manufactured the generic paroxetine that Mr. Dolin actually ingested. In *Bartlett*, the Court held that state-law design-defect claims that turn on the adequacy of a drug's warnings are pre-empted by federal law under *Mensing*. *Bartlett*, 133 S.Ct. at 2471. In light of the Court's holdings in *Bartlett* and *Mensing*, Plaintiff now concedes that her claims against Mylan alleging that Mylan failed to make proper warnings or to make design changes are preempted by federal law and must fail.

Plaintiff maintains, however, that her claim that Mylan breached its duty by failing to issue "Dear Doctor" letters to physicians with updates as to the "true" nature of the risks associated with paroxetine remains viable. I disagree.

It is true that, consistent with *Mensing*, generic manufacturers are permitted to send such

letters to physicians containing important information about drugs, so long as the content of the letters is "consistent with and not contrary to" the drug's approved labeling. *PLIVA*, 131 S.Ct. at 2576. Plaintiff argues that the "Dear Doctor" letter she would have had Mylan send would satisfy *Mensing*, but I do not see how that could be true.

Plaintiff alleges that Mylan knew that paroxetine's post-2007 label did not include any warning of the risk of adult suicidality, and further alleges that Mylan knew it should have contained such a warning. Plaintiff asserts that Mylan should have sent letters to physicians "indicating that paroxetine's adult suicidal behavior risk was higher than the class-wide risk contained in the label."

But Plaintiff does not explain (and I do not see) why such a letter would not be inconsistent with and contrary to paroxetine's approved warning label. The message Plaintiff seeks to have had communicated is that paroxetine's approved warning label was inaccurate and misleading: "contrary" to the approved label, there is indeed an increased risk of suicidality for adults. These "Dear Doctor" letters are considered "labeling" under FDA regulations, and Mylan, as a generic manufacturer, was prohibited from making any such labeling changes by the FDA. *See PLIVA*, 131 S.Ct. at 2576. A claim that would have a generic defendant make such changes is thus preempted by federal law. *See Bartlett*, 133 S.Ct. at 2466; *PLIVA*, 131 S.Ct. at 2576.

CONCLUSION

For the foregoing reasons, defendant GSK's motion for summary judgment is granted as to Plaintiff's claim arising under strict liability. GSK's motion for summary judgment is denied as to the remainder of Plaintiff's claims. Mylan's motion to dismiss is granted.

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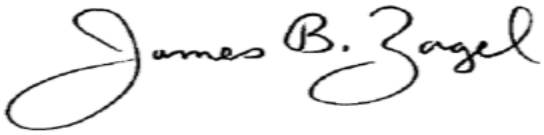

James B. Zagel
United States District Judge

DATE: February 28, 2014